(a) whether Ibuprofen in combination with Mephenesin has been allowed ointment from by the Food and Drug Authority Gujarat for marketing in the country;

(b) whether any study or clinical trial was done on this preparation;

(c) if so, what are the details thereof;

(d) what is the procedure for approval of such products and whether all those procedures have been followed;

(e) what are the names of the countries where such preparation is being marketed;

(f) whether it is a fact that drug authorities in States have refused to give permission for such preparation; and

(g) if so, what is Government policy in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) to (c) Central Drugs Standards Control Organisation has no information whether Ibuprofen in combination with Mephenesin has been permitted in ointment form by the Food & Drug Authority, Gujarat for marketing.

(d) and (e) As per the Guidelines on introduction of New Drugs combination of known drugs would fall under the definition of "New Drugs" and such permission to manufacture and market new drug is required to be granted by the Drugs Controller, India. However, the guidelines are not yet statutory and some States have been licencing certain combination of drugs for marketing.

(f) Central Drugs Standards Control Organisation has no information on the names of the countries where such preparation is being marketed.

(g) Government is making the guidelines statutory and permission to manufacture and market all types of combination products would be required to be obtained from the Drugs Controller, India based on the laid down guidelines once these guidelines become statutory.

Marketing of drug for TB

159. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the names of drugs cleared for marketing in the country for treatment of Tuberculosis by drugs Controller of India;

(b) whether it is a fact that a number of combinations of one or more drugs are being marketed in the country for the treatment of Tuberculosis;

(c) if so, what is the composition of these combinations;

(d) whether any of these combinations have been withdrawn from the market or are under process of withdrawal due to irrational combination; and

(e) if so, what are the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) The names of anti-tuberculosis drugs approved to marketing in the country are PAS, Capromycin sulphate Ethambutol, Ethionamide, INH, Morazinamide, Prothionamide, Pyrazinamide, Rifampicin, Thiacetazone, Terizidone and Cycloserine.

(b) and (c) The combination of drugs marketed in the country for the treatment of tuberculosis are:

1. Rifampicin 450 mg * INH 300 mg—strip of 4 capsules

2. Etnambutol 800 mg INH 300 mg—strip of 10 tablets

3. Sodium PAS 834 mg+INH 25 mg- a bottle of 100 tablets

4. Thiacitazone 150 mg.+INH 300 mg- a pack of 10 tablets.

5. Streptomycin sulphate 1 gm+ Sodiumethanesulfonate of INH 300 mg per each vial-each vial.

(d) and (e) All combinations of anti-tubercular drugs other than Refampicin and INH are being reviewed by a Sub-committee of experts from the angle of rationality and whether such combinations merit continued marketing. The review/ examination, however, is not complete and the recommendations of the sub-committee will be examined by the Government for taking a final decision in the matter.

Recommendation of the tetracycline and Hydrocortisone for eye treatment

160. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that eye-drops and eye ointments based on Oxytetracycline chlorotetracycline, Demethy-Chlorotetracycline, Gentamycin, Framycetin Betamethasone and Dexamthasone are being used for Trachoma Control Programme and contro of blindness;

(b) whether the Ministry had recommended only Hydrocortisone and Tetracycline for the said programmes;

(c) what are the criteria/basis on which Tetracycline and Hydrocortisone were identified for inclusion under category I under these programmes and other drugs referred to in part (a) above were excluded;

(d) what is the therapeutic indication of eye ointment and eye drops based on each drug and in what manner one differs from the other; and

(e) what are the indications for which central drug authorities have allowed marketing of eye drops and ointments based on each drug?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) The drugs Oxytetracycline, chlorotetracycline, Demethyl-Chlorotetracycline, Gentamycin, Framycetin, Betamethason and Dexamethasone can be used for Trachoma Control Programme and Control of Blindness.

(b) Yes, Sir.

(c) Since the rationale for using antibiotics is to control infection of the eyes and steriods for control of inflammation and since there is not much difference in the spectrum of action amongst the broad spectrum antibiotics and there is hardly any difference in mechanism of action between the two steriods, namely Betamethasone and Dexamethasone it was decided to recommend one antibiotic namely tetracycline and one steriod namely Hydrocortisone under Category-I to meet one of the overall objective of the New Drug Policy, viz. to reduce the span of price control on drugs.

(d) and (e) The therapeutic indication for the antibiotics named in the question is to control infection of eyes, and for the steriods drug ointments is to control inflammation for which indications, these drugs have been approved by the Central Drug Control Authority.

Monitoring and control on the misleading advertisement on the drug

161. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is any Government machinery to monitor and control misleading advertisements of drugs;